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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/758,799 | 01/11/2001 | Thomas R. Porter | P00639US3 | 1046 |

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT PAPER NUMBER

1617

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 09/758,799 | Applicant(s) PORTER, THOMAS R. | |
| | Examiner Shahnam Sharareh | Art Unit 1617 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 53-69 and 71-82 is/are pending in the application.
- 4a) Of the above claim(s) 53-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 66-69 and 71-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's submission filed on June 15, 2004 has been entered. Claims 53-69, 71-82 are pending. Claims 66-69, 71-82 are under consideration. Claims 53-66 stand withdrawn pursuant to the Applicant's election filed on September 06, 2002.

Any rejection that is not addressed in this Office Action is considered obviated in view of the amendments and arguments.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 66-69, 71-78, 82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 66 recite the limitations of "applying ultrasound to the vessels in the area of trauma," but the same step requires the ultrasound to be applied "distal to the thrombus site." Such requirements in the same step appear contradictory to each other and render the scope of the claims vague.

At one point the claims appear to suggest that the ultrasound needs to be applied in the area of trauma to the vessels in the area of trauma which has led to the thrombus. On the other hand, claims require the ultrasound to be distal to the thrombus which is viewed to be away from the thrombus and subsequently away from the vessels in the area of trauma. Therefore, the relative location of

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the source of the ultrasound energy is not clear and thus neither is the scope of the claims.

Claim 82 describes the limitation "close to and not on the thrombus." This limitation appears relative in nature. The specification fails to set forth a qualitative measurement of such limitation. What distance from the thrombus is encompassed by this limitation? Such descriptive limitation is a subjective measurement, is open to interpretation and fails to describe the metes and the bounds of the claim.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 66-69, 71-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siegel in view of Tachibana et al US Patent 5,315,998, Feinstein US Patent 4,718,433 and further in view of Schutt US Patent 5,605,673 (Schutt).

Applicant's arguments with respect to this rejection have been fully considered but are not found persuasive.

As the initial matter, Examiner states that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Here, the rejection is based on the combined teachings of the

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references. Thus, describing the shortcomings of one does not amount to evidence of nonobviousness.

Further, Applicant's position that Siegel does not teach the limitation of "applying ultrasound to the vessels in the area of trauma, distal to the thrombus site," is not accurate, because the application of ultrasound by Siegel falls within the scope of the instant claims.

Siegel clearly administer his compositions into blood vessels of rabbits. (col 4, lines 22-27 and examples VII-X; col 8-10). The thrombus of Siegel is formed in a vessel area, because they are arterial occlusions occurring in bilateral iliofemoral arteries (see figure 2). Since Siegel discloses administration of ultrasonic energy within the trauma area, the source of the ultrasound energy falls within the limitations of the instant scope, because it must be applied to the vessels within the area of the arterial occlusion. (see col 4, line 48-col 5, line 20; col 13, claim 3).

Further, the recitation of "distal to the thrombus site" is not defined in the specification; thus, it is given its broadest reasonable interpretation consistent with its plain meaning in the art. Examiner views such limitations to mean "distant or away from the thrombus site."¹ Since such limitation appears relative in nature, Siegel's application of ultrasound energy and location of the source of such ultrasound energy in relation to the thrombus is viewed to fall within the scope of the instant claims, because Siegel applies the ultrasound

¹ This interpretation is consistent with Applicant's interpretation set forth in the Amendment filed on June 15, 2004, pages 8-9.

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intravascularly, within iliofemoral arteries and the soft tissues between the ultrasound transducer and the occlusion. (see col 9, lines 20-29; claim 3).

Moreover, aside from Applicant's arguments that Siegel fails to literally apply his ultrasound energy on vessels in the area of trauma, applicant has not provided any evidence showing any difference in the outcome or efficacy of the instant claims and those suggested by the combined teachings of the cited references. Examiner views the method of Siegel to provide the same or a similar function in a substantially similar way as those instantly claimed, even though Siegel does not described in the exact literal words the location of the ultrasound source.

Siegel uses microbubbles and ultrasound energy for the same purpose as the instantly claimed methods. Siegel's microbubbles contain the same gaseous entities as those instantly claimed. (see Siegel at col 10, lines 1-10). Siegel discloses the use of Albunex as the suitable sonicated albumin. Albunex contain microbubbles having average diameter size within 2-10 micron (see de Jong abstract, Ultrasonic 1993; 31(3): 175-181). Siegel only fails to specifically disclose the optimal concentrations for the albumin and a Dextrose carrier.

However, the secondary references, Tachibana and Feinstein, collectively set forth the function of such concentrations for employing albumin and a dextrose carrier system to persons of ordinary skilled in the art. Tachibana 5% dextrose in combination with streptokinase (see col 6, line 15-col 8, line 5). Feinstein teaches methods of formulating Albunex echo contrast agent and applying it to a traumatized coronary tissue. (see abstract, col 5, line 45-col 6,

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line 40; col 8, lines 1-49). col 2, lines 46-68, col 8, lines 1-46). Feinstein also acknowledge the use of their contrast agents in treating blood flow abnormalities (see col 8, lines 1-10). Thus, all elements of the claims are described by the combined teachings of the references and the rejection is deemed to be proper.

3. The new claims 79-82 are also rejected over Siegel in view of Tachibana, Feinstein, and Schutt. Claim 79 recites the new limitation of applying ultrasound to the microbubble composition following its injection and during transit to the thrombus. Since Siegel teaches administering his microbubble composition into vessels, and the blood within such vessels is always in transit within the circulatory system, application of the Ultrasound energy in Siegel's methodology inherently occurs during the transit of the microbubble composition from the injection site to the thrombus.

Claim 82 also recites a new limitation of "applying ultrasound to the vessels in the area of trauma, close to and not on the thrombus site." Siegel methods meet such limitation, because Siegel teaches applying the ultrasound energy transcutaneous to the thrombus site. Examiner construes such teachings to be close to but not on the thrombus site. Further, Siegel claims intravascular administration of ultrasound energy. Therefore, Siegel meets the limitations of claim 82.

Accordingly, all limitations of the instant claims are described by the combined teachings of the references and the rejection is maintained.

Conclusion

No claims are allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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